Hongye Plastic Products Co., Ltd
Donggao Industrial Zone Zanhuang, Hebei, China 050000

JAN 17 2013

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K122408

1. **Owner's Identification:**
   Ms. Liu Yingxue
   Hongye Plastic Products Co., Ltd.
   Donggao Industrial Zone,
   Zanhuang, Hebei, China 050000
   Tel: 86-311-83980319

   Submitter and Contact person: Kathy Liu
   Address: 3973 Schaefer Ave., Chino, CA 91710
   Tel: 909-590-1611
   Fax: 909-590-1511
   Date Summary Prepared: July 30, 2012

2. **Name of the Device:**
   Hongye Plastic Products Co., Ltd.
   Powder Free Nitrile Examination Gloves (Black, White, Green)
   Common Name: Exam Gloves

3. **Predicate Device Information:**
   Hong Xin Rubber Products Co., Ltd
   Powder Free Nitrile Examination Gloves, Blue (K070861)

4. **Device Description:**
   Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Polymer Patient Examination Gloves, 80 LZA, and meets all requirements of ASTM standard D 6319-10.

5. **Intended Use of the Device:**
   A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6. **Comparison to Predicate Devices:**
Hongye Plastic Products Co., Ltd.'s Powder Free Nitrile Examination Gloves (Black, White, Green) is substantially equivalent in safety and effectiveness to the Hong Xin Rubber Products Co., Ltd's Powder Free Nitrile Examination Gloves, Blue.

Characteristics		Standard	Device Performance		Result of comparison
			Predicate device	Subject Device	
Product Code		/	LZA	LZA	Substantial equivalence
Intended Use		/	Predicate device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Subject device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Substantial equivalence
Labeling		/	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	Substantial equivalence
Device Materials		/	Nitrile compound	Nitrile Compound	Substantial equivalence
Color		/	Blue	Black, White, Green	Different, it have been confirmed to be safety for use
Device tolerances and specifications	Tensile strength: before and after aging	ASTM D6319-10	Meets	Meets	Substantial equivalence

Characteristics		Standard	Device Performance		Result of comparison
			Predicate device	Subject Device	
Device tolerances and specifications	Ultimate elongation: before and after aging	ASTM D6319-10	Meets	Meets	Substantial equivalence
	Freedom from pinholes	ASTM D6319-10	Meets	Meets	Substantial equivalence
	Dimensions: Overall length, Width, Palm and Finger thickness	ASTM D6319-10	Meets	Meets	Substantial equivalence
	Residual powder	ASTM D6319-10, ASTM D6124	Meets	Meets	Substantial equivalence
Performance data	Tensile strength: before and after aging	ASTM D6319-10	Meets	Meets	Substantial equivalence
	Ultimate elongation: before and after aging	ASTM D6319-10	Meets	Meets	Substantial equivalence
	Freedom from pinholes	ASTM D6319-10	Meets	Meets	Substantial equivalence
	Dimensions: Overall length, Width, Palm and Finger thickness	ASTM D6319-10	Meets	Meets	Substantial equivalence
	Residual powder	ASTM D6319-10 & ASTM D6124	Meets	Meets	Substantial equivalence

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
Biocompatibility	Primary skin irritation test	Passes Not a primary skin irritation	Passes Not a primary skin irritation	Substantial equivalence
	Dermal sensitization assay	Passes Not a dermal sensitization	Passes Not a dermal sensitization	Substantial equivalence

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:**

Characteristics	Applicable FDA- Recognized Standards	Performance Results
Dimensions	ASTM D 6319-10	Meets
Physical Properties	ASTM D 6319-10	Meets
Freedom from holes	ASTM D 6319-10	Meets
Residual Powder Test	ASTM D 6319-10 ASTM D6124-06 (Reapproved 2011)	Meets
Primary Skin Irritation and Skin Sensitization	ISO 10993 Part 10 16CFR 1500.41 16CFR 1500.3	Meets

8. **Labeling:**
There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels.

9. **Discussion of Clinical Tests Performed:**
Not Applicable – There is no hypoallergenic Claim.

10. **Conclusions:**
Hongye Plastic Products Co., Ltd.'s Powder Free Nitrile Examination Gloves (Black, White, Green) conform fully to ASTM D6319-10 standard as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited. Drawn from the complete list of non-clinical tests, the device herein mentioned is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2013

Hongye Plastic Products Company, Limited
C/O Ms. Kathy Liu
Project Manager
Surprotect, Incorporated
3973 Schaefer Avenue
CHINO CA 91710

Re: K122408
Trade/Device Name: Powder Free Nitrile Examination Gloves (Black, White, Green)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: November 26, 2012
Received: November 27, 2012

Dear Ms. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Hongye Plastic Products Co., Ltd
Donggao Industrial Zone Zanhuang, Hebei, China 050000

Attachment A

INDICATION FOR USE

510 (k) NUMBER (IF KNOW): K122408
APPLICANT: Hongye Plastic Products Co., Ltd.
DEVICE NAME: Powder Free Nitrile Examination Gloves (Black, White, Green)

INDICATIONS FOR USE:

A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/ OR Over-The-Counter-Use ___√___.
(Part 21 CFR 801 Subpart D) (21CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Elizabeth F. Claverie _____ _____ _____ _____ _____
2013.01.16 14:53:22 -05'00' Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122408